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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/625,196

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Guido Guglielmi

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

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DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/625,196

Applicant(s)

GUGLIELMI ET AL.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29-52, 54, 55 and 57-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-52, 54, 55 and 57-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This action is in response to applicant's amendment received 06 July 2007.

The examiner acknowledges the amendments made to the claims.

#### *Claim Objections*

1. Claim 57 is objected to because of the following informalities: It is dependent on Claim 53, which is currently a canceled. Claim 57 must be amended to depend from an existing claim. Appropriate correction is required.

#### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 29-36, 44-46, 54-55, 57-61, 64-65, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**) in view of **Alt** (U.S. Patent No. **6,238,340**).

Claim 29: Scheldrup discloses a catheter **158** having a proximal end and a distal end, the catheter being capable of being inserted into a vascular cavity in the body, a delivery member **102**, a temporary connection **106** joining an implant and a distal end of

the delivery member, and an electrical measurement device, wherein the electrical measurement device is configured to monitor an electrical condition related to a position of the temporary connection while the temporary connection is joined to the implant and delivery member, the electrical condition changing when the temporary connection reaches a predetermined location as the delivery member is advanced through the catheter, the electrical measurement device configured to generate an output signal in response to the changed electrical condition, the output signal indicating that the temporary connection has reached the predetermined location (Figures 3-5, and col. 4, lines 1-33 and col. 6, lines 36-62 and col. 7, lines 39-48, col. 10, lines 30-44).

Scheldrup does not expressly disclose that the temporary connection must be joined to the implant while the electrical output signal is generated by the electrical measurement device, although Scheldrup discloses that the device is capable of detecting a condition that may not be a result of dissolution of the temporary connection (col. 4, lines 24-33).

Alt teaches positioning or implanting a device **10** into a patient, and when a connection **15** makes electrical contact with tissue or fluids of the body, an electrical signal is sensed by an electrical measurement device while the connection is joined to the implant (Figure 1, col. 4, lines 29-57). It would have been obvious to one of ordinary skill in the art at the time of invention to provide the output signal while still being connected to the implant, as taught by Alt, to Scheldrup, since it was known in the art to utilize electrical conductivity for communicating signals for positioning devices.

Claims 30-31: Scheldrup discloses the delivery member comprising a delivery wire, or a tubular body **102** (Figure 3).

Claim 32: Scheldrup discloses the temporary connection comprising an electrolytic connection (col. 4, lines 34-42).

Claim 33: Scheldrup discloses a power supply **170** configured to provide electric current, the electrolytic connection being broken by current provided by the power supply through the delivery member and the temporary connection to corrode a portion of the temporary connection (Figures 4-5, and col. 4, lines 1-24).

Claim 34: Scheldrup discloses the corrodible portion of the temporary connection being corroded comprising a stainless steel portion of the delivery member that is exposed to blood in the vascular cavity in the body (col. 5, lines 49-55).

Claims 35-36: Scheldrup discloses the electrical monitoring device **300** being included in ("integrated with") the power supply and separate from the power supply (Figures 6-7 and col. 5, lines 1-3).

Claims 44-45: Scheldrup discloses the implant comprising a vaso-occlusive implant, which also comprises a coil (col. 1, lines 1-19 and col. 6, lines 1-11).

Claim 46: Scheldrup discloses the coil comprising a Guglielmi Detachable Coil (GDC) (col. 12, lines 19-33).

Claims 54-55: Scheldrup discloses a visual indicator, the electrical measurement device being configured to provide the output signal to the visual indicator so that the visual indicator can be illuminated after the electrical condition has changed (Figure 6 and col. 7 line 49 to col. 8, line 33), and an audio indicator, the electrical measurement

device being configured to provide the output signal to the audio indicator so that the audio indicator can be activated after the electrical condition has changed (col. 10, lines 30-44).

Claim 57: Scheldrup discloses the output signal being provided to a controller **300**, the electrical measurement device being configured to provide the output signal to the controller, the controller being configured to automatically break the temporary connection in response to the output signal after the electrical condition has changed (Figure 6, col. 8, lines 40-49).

Claim 58: Scheldrup discloses insulative members **112** and **110** (Figure 2, col. 6, lines 1-22). Although Scheldrup does not disclose an insulation member between the implant and the temporary connection, it would have been obvious to one of ordinary skill in the art to provide an insulation member between the implant and the temporary connection to focus electrolysis on a targeted, specific location.

Claims 59-61: Scheldrup discloses the predetermined position comprising the distal end of the catheter and the electrical condition changing when the temporary connection reaches or extends beyond the distal end of the catheter (col. 7, lines 20-48).

Claims 64-65: Scheldrup discloses a conductive wire connected between the electrical measurement device and the distal end of the catheter, the conductive wire being inserted through the catheter, the electrical measurement device being configured to detect an electrical condition related to a position of the temporary connection in the

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catheter through the conductive wire, and the electrical monitoring device comprising a volt/current meter (Figures 4-6).

3. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**) and **Alt** (U.S. Patent No. **6,238,340**), as applied to Claim 29 above, and further in view of **Palermo** (U.S. Patent No. **5,250,071**).

Claim 37: Scheldrup and Alt disclose the claimed device as discussed above, except for a temporary mechanical connection.

Palermo teaches an embolic coil with a temporary mechanical connection (col. 2, lines 63-67 and col. 3, lines 1-18). It would have been obvious to one of ordinary skill in the art to provide a temporary mechanical connection, as taught by Palermo, to Scheldrup and Alt, since it was known in the art that temporary mechanical connections are common in detachable surgical implants that extend to filters and stents.

4. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**) and **Alt** (U.S. Patent No. **6,238,340**), as applied to Claim 29 above, and further in view of **Guglielmi** (U.S. Patent No. **5,569,245**).

Claims 38-39: Scheldrup and Alt disclose the claimed device, as discussed above, except for the temporary connection comprising a temporary connection that is breakable by application of heat and radio frequency (RF) radiation.

Guglielmi teaches a temporary connection that is breakable by application of heat and radio frequency (RF) radiation (col. 3, lines 10-20). It would have been

obvious to one of ordinary skill in the art to provide a temporary connection broken by heat and RF radiation, as taught by Guglielmi, to Scheldrup and Alt, since it was known in the art that heat and RF radiation are effective detachment sources and commonly break connections, joints, or attachments in surgical devices.

5. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**) and **Alt** (U.S. Patent No. **6,238,340**), as applied to Claim 29 above, and further in view of **Sepetka** (U.S. Patent No. **5,814,062**).

Claim 40: Scheldrup and Alt disclose the claimed device as discussed above, except for the temporary connection comprising a temporary connection that is hydraulically broken.

Sepetka teaches a temporary connection that is hydraulically broken (col. 3, lines 10-26). It would have been obvious to one of ordinary skill in the art to provide a temporary connection that is hydraulically broken, as taught by Sepetka, to Scheldrup and Alt, since it was known in the art that fluid pressure is commonly used to disconnect temporary detachments between embolic coils and delivery members.

6. Claims 41-43, and 47-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**) and **Alt** (U.S. Patent No. **6,238,340**), as applied to Claim 29 above.

Claims 41-43: Scheldrup and Alt disclose the electrical condition comprising an impedance (col. 4, lines 1-24). Although Scheldrup does not disclose the electrical



condition being current in this embodiment, Scheldrup acknowledges that in another example, current may be monitored (col. 12, lines 42-46).

Claims 47-50: Scheldrup discloses the coil including platinum (col. 5, lines 38-50).

Although Scheldrup does not disclose the coil having a bio-reactive material coating or the coil being a non-bio-reactive polymer coil, it would have been obvious to one of ordinary skill in the art to provide the claimed materials, since it was known in the art that a coating of bio-reactive material may aid in the endovascular embolism or occlusion and non-bio-reactive polymer coils can remain longer within the body without having to be surgically removed.

Claims 51-52: Scheldrup discloses the claimed device except for the implant comprising a stent or a filter. It would have been obvious to one of ordinary skill in the art to provide a stent or a filter as the implant, since it was known in the art that vaso-occlusion is commonly achieved by filters and stents.

7. Claims 62-63, 67-71, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scheldrup** (U.S. Patent No. **5,669,905**) and **Alt** (U.S. Patent No. **6,238,340**), as applied to Claim 29 above, and further in view of **Cheng** (U.S. Patent No. **6,296,636**).

Claims 62-63 and 67: Scheldrup and Alt disclose the claimed device as discussed above (Figure 11 and col. 11, lines 24-34), including measuring an electrical current as the delivery member is pushed through the catheter and the electrical current being related to a relative position of the temporary connection before the temporary

connection is broken (when it is at a pre-determined location), except for the electrical measurement device including a current measurement device configured to monitor the electrical current and a comparison circuit, the electrical current being related to a relative position of the temporary connection before the temporary connection is broken, the comparison circuit being configured to compare a reference or threshold current to a second current measured by the electrical measurement device, the comparison circuit being further configured to generate the output signal when the temporary connection has reached the predetermined location and the measured current or second current is larger than the reference or threshold current.

Cheng teaches an electrical measurement device including a current measurement device configured to monitor the electrical current and a comparison circuit, the comparison circuit being configured to compare a threshold current to a current measured by the electrical measurement device, the comparison circuit being further configured to generate the output signal when the temporary connection has reached the predetermined location and the measured current is larger than the threshold current – the output indicating limiting power (col. 5, lines 15-34). Cheng teaches that limiting power during electrosurgery to avoid overcurrents or sparks that may occur is effectively prompted by using reference and measured currents (col. 3, lines 48-55). It would have been obvious to one of ordinary skill in the art to provide an electrical measurement device including a comparison circuit that compares a threshold current to a current measured by the electrical measurement device which is larger than the threshold current, as taught by Cheng, to Scheldrup in order to obtain a desired

output signal, which may limit power during electrosurgery to avoid overcurrents or sparks, which is effectively prompted by using reference and measured currents.

Claim 68: Scheldrup discloses the temporary connection can be broken electrolytically after the output signal is generated (col. 4, lines 34-42).

Claims 69-70: Scheldrup discloses a visual indicator, the electrical measurement device being configured to provide the output signal to the visual indicator so that the visual indicator can be illuminated after the electrical condition has changed (Figure 6 and col. 7 line 49 to col. 8, line 33), and an audio indicator, the electrical measurement device being configured to provide the output signal to the audio indicator so that the audio indicator can be activated after the electrical condition has changed (col. 10, lines 30-44).

Claim 71: Scheldrup discloses the output signal being provided to a controller 300, the electrical measurement device being configured to provide the output signal to the controller, the controller being configured to automatically break the temporary connection in response to the output signal after the electrical condition has changed (Figure 6, col. 8, lines 40-49).

### ***Response to Arguments***

8. Applicant's arguments with respect to claims 29-52, 54-55, and 57-71 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", with a stylized, cursive script.

MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER